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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,082	04/14/2004	Dino J. Farina	3558.1000-001	7176
21005 7590 05/26/2009 HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133				
EXAMINER				
GISSEL, GUNNAR J				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/825,082

Applicant(s)

FARINA ET AL.

Examiner

Gunnar J. Gissel

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/27/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 19-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-15, 17, 18, 38 and 39 is/are rejected.
- 7) ☒ Claim(s) 5, 6 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 4, 7, 11, 14, 15, 17, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6,148,815 to James Wolf (Wolf).

Regarding Claim 1, Wolf discloses an apparatus for providing information about operation of a spray device, the apparatus comprising: an adapter assembly configured to be coupled to a movable part of a spray device (Wolf, figure 2); a mounting assembly configured to be coupled to a stationary part of the spray device (Wolf, figure 3); a transducer coupled to the mounting assembly or the adapter assembly (Wolf, column 18, lines 27-35) and a linkage (Wolf, linkage 1555), adapted to extend between the mounting assembly and the adapter assembly, in operational relationship with the transducer to enable the transducer to indicate a mechanical relationship between the movable and stationary parts of the spray device corresponding to operation of the spray device (Wolf, column 18, lines 27-36). Strain gauge is defined as "A transducer/sensor that determines pressure by measuring electrical resistance variations in a stressed wire." (Academic Press Dictionary of Science and Technology). Linkage is defined as "the act of linking; state or manner of being

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linked,” and link is defined as “anything serving to connect one part or thing with another.” (linkage. (n.d.). *Dictionary.com Unabridged (v 1.1)*. Retrieved May 14, 2009, from Dictionary.com website:

<http://dictionary1.classic.reference.com/browse/linkage> ; link. (n.d.).

Dictionary.com Unabridged (v 1.1). Retrieved May 14, 2009, from Dictionary.com website: <http://dictionary1.classic.reference.com/browse/link>).

Regarding Claim 4, Wolf discloses a base assembly adapted to couple to the mounting assembly, the base assembly including a foot assembly with a footprint that supports the spray device in a vertical relationship with the foot assembly (Wolf, figure 2).

Regarding Claim 7, Wolf discloses that the transducer is a position sensor (Wolf, transducer 1555; column 22, lines 60-63).

Regarding Claim 11, that the spray device is a Metered Dose Inhaler (MDI) (Wolf, column 3, lines 14-20).

Regarding Claim 14, Wolf discloses a data processing system coupled to the transducer that captures indications of the mechanical relationship between the movable part and the stationary part (Wolf, column 3, lines 65-67; column 22, lines 60-63).

Regarding Claim 15, Wolf discloses that the data processing system includes program instructions that automatically calculate parameters in position, velocity, or acceleration corresponding to operation of the spray device (Wolf, column 22, lines 60-63; column 23, lines 20-27).

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Regarding Claim 17, Wolf discloses that the parameters include at least one of the following: maximum position displacement, hold time, maximum actuation velocity, maximum return velocity, maximum actuation acceleration, and maximum return acceleration (Wolf, column 22, lines 60-63; column 23, lines 20-27).

Regarding Claim 18, Wolf discloses that the data processing system includes a signal conditioner (Wolf, signal conditioner 855), data sampler (Wolf, data sampler, (Wolf, data sampler 605), and amplifier (Wolf, amplifier 820), wherein the signal conditioner conditions a signal effected by the transducer prior to the data sampler and amplifier operating on the signal (Wolf, figure 8, transducer 1555).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 2, 3, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf in view of US Patent 5,579,659 to Jeffrey Roberts (Roberts).

Regarding Claims 2, 3, 8 and 9, Wolf discloses an apparatus, but does not explicitly disclose a bearing and shaft assemble, or that the bearing and shaft

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assembly substantially maintains alignment or that the position sensor is a potentiometer or that the linkage is spring loaded.

Roberts discloses that the mounting assembly includes a bearing and shaft assembly coupling the adapter assembly to the mounting assembly (Roberts, column 4, lines 3-14) and that the bearing and shaft assembly substantially maintains alignment between the adapter assembly and the mounting assembly in non-actuation axes (Roberts, figures 1 and 3) that the position sensor is a potentiometer (Roberts, column 4, lines 3-14) and that the linkage is a spring loaded wire integrally associated with the potentiometer (Roberts, column 4, lines 3-14)).

It would have been obvious to one of ordinary skill in the art to combine the teachings of Roberts with the apparatus of Wolf because Roberts teaches a way of verifying the operation of the spring used in testing a device (Roberts, column 1, lines 10-14)

4. Claims 10, 12, 13, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf with teachings from US Patent application publication 2005/0016527 to Lee Barger et al. (Barger).

Regarding Claims 10, 12, 13, 38 and 39 Wolf discloses the apparatus, but does not explicitly disclose that the adapter assembly is configured to interface with an automated actuation system or that the transducer indicates the mechanical relationship in a format usable by the automated actuation system or that the spray device is a nasal spray bottle, or that the automated actuation

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system includes a compression plate or that the compression plate includes a force transducer.

Barger discloses that the adapter assembly is configured to interface with an automated actuation system that operates the spray device in an automated manner (Barger, paragraph 17) and that the transducer indicates the mechanical relationship in a format usable by the automated actuation system (Barger, paragraph 32) and that the spray device is a nasal spray bottle (Barger, paragraph 2) and that the automated actuation system includes a compression plate assembly connected to a drive plate assembly, the compression plate assembly pressing upward on the stationary part of the spray device in response to upward force by the drive plate assembly (Barger, figure 5) and that the compression plate assembly includes a force transducer positioned to sense actuation force of the spray device caused by the upward force applied to the compression plate assembly by the drive plate assembly (Barger, figure 5, transducer 148).

It would have been obvious to one of ordinary skill in the art, at the time of the invention, to combine the teachings of Barger with the apparatus of Wolf because Barger teaches automated testing of MDI devices can determine how effective they are at dispensing medication into a patient's airway, as opposed to a patient's throat (Barger, paragraph 8).

Allowable Subject Matter

5. Claims 5, 6 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

6. Applicant's arguments filed 2/27/2009 have been fully considered but they are not persuasive. Applicant argues that the strain gauge sensing arm does not constitute a linkage because it is not connected at both ends. Given the definition of "Linkage" cited above, connecting an arm at both ends is not strictly necessary for the arm to be considered linkage. The sensing arm touches the vial/canister and is able to determine how far the vial/canister is depressed because the sensing arm's position and motion are directly effected by the vial/canister's motion. The sensing arm in Wolf connects the vial/canister with the strain gauge, which is a link, which makes the sensing arm a linkage. Applicant makes a similar argument with regard to Roberts, and the definition and requirements for what constitute a linkage are the same for Robert as they are for Wolf, as described above.

7. Applicant argues that Wolf does not calculate the parameters of position, velocity, acceleration, maximum position displacement, hold time, maximum actuation velocity, maximum return velocity, maximum actuation acceleration or maximum return acceleration. The examiner notes that Applicant phrased claims 15 and 17 in the alternative, so it is only necessary for Wolf to show any one of the claimed parameters. Wolf, in figures 19a through 19e shows the position of

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the canister as well as the maximum displacement and hold time. Wolf, in column 22, lines 60 to column 23, line 27 describes how the information recorded by the sensing package is retrieved, and how the recorded information indicates what Wolf calls "premature deliver, delayed delivery and proper dispensation." Wolf describes how the device characterizes these terms in column 20, line 15 through column 21, line 60. Wolf clearly uses the data from the instrument to create the "canister position" line, which directly tracks canister position, maximum position displacement and hold time.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gunnar J. Gissel whose telephone number is

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(571)270-3411. The examiner can normally be reached on Mon-Fri, 7:30AM-5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (571)272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GJG/

/Hezron Williams/
Supervisory Patent Examiner, Art
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5/14/2009